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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,340	01/23/2004	Timothy A. Hagen	PC25240A	7074

28523 7590 05/23/2005

PFIZER INC.
PATENT DEPARTMENT, MS8260-1611
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EXAMINER	
HAWES, PILI ASABI	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/763,340	HAGEN ET AL.	
	Examiner	Art Unit	
	Pili A. Hawes	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-19,21-38,49-74 and 76-91* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-19,21-38,49-74 and 76-91* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

J. O. D.

DETAILED ACTION

Summary

Receipt of the Information Disclosure Statements filed 6-18-2004 and 2-28-2005 is acknowledged. Claims 1-15, 39-48, 75 and 92-114 have been cancelled. Claims 16-19, 21-38, 49-74, and 76-91 are pending in this action. Claims 16-19, 21-38, 49-74, and 76-91 are rejected.

Election/Restrictions

Claims 75, and 108-114 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 5-2-2005.

Applicant's election without traverse of the bicarbonate or phosphate as the alkalizing agents and powder as the dosage form in the reply filed on 5-2-2005 is acknowledged.

Priority

It is noted that this application appears to claim subject matter disclosed in prior Application No. 60/527084, filed 12-4-2003. A reference to the prior application must be inserted as the first sentence(s) of the specification of this application or in an application data sheet (37 CFR 1.76), if applicant intends to rely on the filing date of the prior application under 35 U.S.C. 119(e) or 120. See 37 CFR 1.78(a). For benefit claims under 35 U.S.C. 120, the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of all nonprovisional applications. Also,

the current status of all nonprovisional parent applications referenced should be included.

If the application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference to the prior application must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director

may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

Specification

The abstract of the disclosure is objected to because the title of the abstract does not meet the requirements as set forth in the MPEP § 608.01(b). The current title, "Abstract of the Invention" needs to be changed to "Abstract" or "Abstract of the Disclosure". Correction is required. See MPEP § 608.01(b).

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, **such as "means" and "said,"** should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The word said appears in lines 6, 7, 14, 19, 21 and 24. Correction is required.

The disclosure is objected to because of the following informalities: there are blanks in the specification on page 21 lines 14 and 28. The US patent application serial number is missing.

Appropriate correction is required.

Claim Objections

Claims 33 and 87 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim shall contain a reference, **in the alternative only**, to more than one claim previously set forth and then specify a further limitation of the subject matter claimed. A multiple dependent claim shall not serve as a basis for any other multiple dependent claim. A multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered. See MPEP § 608.01(n).

Claim Rejections - 35 USC § 102

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 16-18, 21-23, 36, 49-55, 60, 61-68, 70-73, 76-82, 87, 90 and 91 rejected under 35 U.S.C. 102(b) as being anticipated by Curatolo et al. US 6068859.

Curatolo discloses an oral dosage form of azithromycin comprising an alkalizing agent, a wax, and a glyceride (col. 7, 15-47). Curatolo discloses modified vegetable oils, carnauba wax, hydrogenated castor oil, and beeswax (col. 7, 30-32). The reference also discloses the use of a dissolution agent, such additives are sugars, salts, soluble polymers, and alcohols (col. 8, 49-55). Sodium lauryl sulfate is disclosed in the tablet core formulation in Table 31 (col. 54, 22-35). Table 31 also discloses azithromycin is in the from of a dihydrate as is claimed in claim 36. Table 31 also discloses a phosphate alkalizing agent, specifically calcium phosphate dibasic. The oral dosage formulation disclosed in the prior art yields lower incidence of gastrointestinal side effects (col. 1,

50-58). The prior art also discloses a method of treating microbial infections using the azithromycin formulation (col. 1, 13). The oral formulation is for administration to a human (col. 1, 15). Example 1 discloses a single 2 g oral dose of azithromycin being administered (col. 29, 15-20). This amount of azithromycin falls within the range 250 mg-7g of azithromycin, and anticipates the ranges 1.5-4 g, 1.5-3 g, and 1.8-2.2 g. Example 15 discloses comparative example of an immediate release and delayed release formulation of azithromycin (col. 45, 30-60).

Claim 87 objected to above for being in improper multiple dependent form is interpreted to depend on claim 76. Therefore the limitations of claims 87, 90 and 91 are met as discussed above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 16-19, 21-38, 49-74, and 76-91 are rejected under 35 U.S.C. 103(a) as being obvious over Curatolo et al. US 6068859 (Curatolo) in view of WO 03/032922 (WO)and further in view of Constantinides et al. US 6479540 B1 (Constantinides).

Curatolo discloses an oral dosage form of azithromycin comprising an alkalizing agent, a wax, and a glyceride (col. 7, 15-47). Curatolo discloses modified vegetable oils, carnauba wax, hydrogenated castor oil, and beeswax (col. 7, 30-32). The reference also discloses the use of a dissolution agent, such additives are sugars, salts, soluble polymers, and alcohols (col. 8, 49-55). Sodium lauryl sulfate is disclosed in the tablet core formulation in Table 31 (col. 54, 22-35). Table 31 also discloses azithromycin is in the from of a dihydrate as is claimed in claim 36. Table 31 also discloses a phosphate alkalizing agent, specifically calcium phosphate dibasic. The oral dosage formulation disclosed in the prior art yields lower incidence of gastrointestinal side effects (col. 1, 50-58). The prior art also discloses a method of treating microbial infections using the azithromycin formulation (col. 1, 13). The oral formulation administered to a human (col. 1, 15). Example 1 discloses a single 2 g oral dose of azithromycin being administered (col. 29, 15-20). Example 15 discloses comparative example of an immediate release and delayed release formulation of azithromycin (col. 45, 30-60). Curatolo suggests that the formulation disclosed could be used in children stating that rates of release of azithromycin in "patients under 50 kg weight, e.g. children" may be better than the rate of release in adults.

Claim 87 objected to above for being in improper multiple dependent form is interpreted to depend on claim 76. Therefore the limitations of claims 87, 90 and 91 are met as discussed above.

Curatolo does not teach all the glycerides listed by applicant. Specifically, the reference does not disclose the use of glyceryl behenate. Curatolo does not disclose the use of poloxamer 407 as a dissolution enhancer. Curatolo also does not disclose the use of magnesium hydroxide and tribasic sodium phosphate as the alkalizing agents.

WO 03/032922 discloses azithromycin powder formulations that contain sodium lauryl sulfate, anti-foaming agents, sweeteners and fillers, and pH buffers (pages 9-10). The reference teaches the specific glyceride, glyceryl behenate (page 8). WO also teaches tribasic sodium phosphate as an additive to maintain pH (page 10). WO does not disclose the use of poloxamer 407.

Constantinides teaches a number of the dissolution agents claimed by applicant (col. 7, 60-67). The reference specifically discloses pharmaceutical formulations comprising poloxamer 407 in combination with macrolide antibiotics such as clarithromycin and erythromycin (col. 9-10). Constantinides teaches poloxamers are surfactants (col. 7, 67). The reference also discloses that azithromycin is a member of the macrolide antibiotic class of drugs (col. 9, 7). Constantinides teaches that macrolide antibiotics are primarily administered orally due to venous irritation when administered as an injection (col. 9, 8).

It would have been *prima facie* obvious to one of ordinary skill in the art to substitute the glyceryl behenate and the tribasic sodium phosphate (WO), and the poloxamer 407 (Constantinides) into the invention of Curatolo because WO teaches that lubricants such as glyceryl behenate are used in making tablet dosage formulations and that pH buffers such as tribasic sodium phosphate would allow for elevation of the pH, which would decrease gastrointestinal side effects, and Constantinides teaches the poloxamers, which are surfactants that are able to be combined with macrolide antibiotics and enhance solubility and release of the antibiotic. Curatolo already teaches the general embodiment of the instant invention, that being a composition comprising azithromycin, waxes and/or glycerides, alkalizing agents, and dissolution enhancers.

Tribasic sodium phosphate and magnesium oxide are both alkalizing agents. Absent a showing of criticality for the combination of these particular alkalizing agents, the prior art already teaches the use of alkalizing agents in an azithromycin formulation. It is within the realm of one of ordinary skill in the art to be able to select the specific alkalizing agents or combination of alkalizing agents to make the specific formulations desired.

Conclusion

Claims 16-19, 21-38, 49-74, and 76-91 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pili A. Hawes whose telephone number is 571-272-8512. The examiner can normally be reached on 8-4:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

P.A. Hawes
Examiner-1615

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